

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF PUERTO RICO

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BAYER AG, et al.,

Plaintiffs

v.

BIOVAIL LABORATORIES, INC.,  
et al.,

Defendants.

CIVIL NO. 98-1282 (RLA)  
CIVIL NO. 98-1340 (RLA)  
CIVIL NO. 98-1494 (RLA)  
CIVIL NO. 98-1768 (RLA)

PROTECTIVE ORDER GOVERNING CONFIDENTIAL INFORMATION

WHEREAS BIOVAIL LABORATORIES, INC. and BIOVAIL CORPORATION INTERNATIONAL, BAYER AG, BAYER CORPORATION and PFIZER INC., the parties to this action (collectively the "parties" and individually a "party"), and likely non-party witnesses possess confidential information which may be disclosed in responding to discovery requests or otherwise in this action and which must be protected in order to preserve the legitimate business interests of the parties, and

WHEREAS the parties have, through counsel, moved for the entry of a Protective Order to prevent unnecessary dissemination or disclosure of such confidential information,

IT IS HEREBY ORDERED that:

1. Definitions

A. The term "Confidential Information" as used in this Order includes all information that the designating party believes

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constitutes or discloses or relates to processes, operations, research, technical or developmental information, production, marketing, sales, shipments or other proprietary data or information of commercial value, including but not limited to trade secrets. It may include without limitation documents produced in these consolidated actions during formal discovery or otherwise; information produced by non-parties which the producing or designating party is under an obligation to maintain in confidence; answers to interrogatories and responses to requests for admission or other discovery requests; deposition, hearing or trial transcripts; affidavits, experts' reports, memoranda of law; and tangible things or objects that are designated confidential pursuant to this Order. The information contained therein and all copies, abstracts, excerpts, analyses, notes or other writings that contain, reflect, reveal, suggest or otherwise disclose such confidential information shall also be deemed "Confidential Information". Information originally designated as confidential pursuant to this agreement ("Confidential Information") shall not retain that status after any ruling by any Court denying such status to it.

B. The term "designating party means the party producing or designating documents or information as Confidential Information under this Order.

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3 C. The term "receiving party" shall mean the party to  
4 whom Confidential Information is produced.

5 Designation of Confidential Information

6 2. Each designating party who produces or discloses any  
7 material that it believes comprises Confidential Information shall  
8 designate the same. In so designating Confidential Information the  
9 designating party shall mark any document containing the information  
10 "CONFIDENTIAL", "CONFIDENTIAL-ATTORNEYS'-EYES-ONLY" or, subject to  
11 the limitations of Paragraph 6 hereof, "CONFIDENTIAL-ATTORNEYS'-  
12 EYES-ONLY-OUTSIDE COUNSEL". When documents or things are produced  
13 for inspection, the documents or things may be collectively  
14 designated as "Confidential", "Confidential-Attorneys'-Eyes-Only" or  
15 "Confidential-Attorneys'-Eyes-Only-Outside Counsel", for purposes of  
16 the inspection, by letter or otherwise, without marking each  
17 document or thing "Confidential", "Confidential-Attorneys'-Eyes-  
18 Only" or "Confidential-Attorneys'-Eyes-Only-Outside Counsel", and  
19 such documents or things will be treated as Confidential Information  
20 under this Order.  
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22 3. If any Confidential Information is produced by a non-party  
23 to this litigation, such a non-party shall be considered a  
24 "designating party" within the meaning of that term as it is used in  
25 the context of this Order and the parties shall be treated as  
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3 receiving parties. Confidential Information that originated with a  
4 non-party and which is subject to a confidentiality obligation may  
5 be designated as "Confidential", "Confidential-Attorneys'-Eyes-Only"  
6 or, subject to the limitations of Paragraph 6 hereof, "Confidential-  
7 Attorneys'-Eyes-Only-Outside Counsel", and shall be subject to the  
8 restrictions on disclosure specified in Paragraphs 7 and 8.

9  
10 4. In the event any designating party produces Confidential  
11 Information that has not been designated confidential or not  
12 correctly designated, the designating party may designate or  
13 redesignate the information to the same extent as it may have  
14 designated the information before production, by a subsequent notice  
15 in writing specifically identifying the redesignated information, in  
16 which event the parties shall henceforth treat such information in  
17 accord with this Protective Order, and shall undertake their best  
18 efforts to correct any disclosure of such information contrary to  
19 the redesignation. No demonstration or proof of error,  
20 inadvertence, or excusable neglect by the designating party shall be  
21 required for such redesignation.

22 5. The parties may use the designation "Confidential-  
23 Attorneys'-Eyes-Only" when, in the reasonable judgment of the  
24 designating party, the information is Confidential Information, and  
25 is too sensitive, valuable, easily misused or difficult to protect  
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3 from misuse to allow a wider circulation. Confidential-Attorneys'-  
4 Eyes-Only information is to be treated in addition with all the  
5 protection applicable to Confidential Information provided in this  
6 Order.

7         6. The parties may use the designation "Confidential-  
8 Attorneys'-Eyes-Only-Outside Counsel" only for documents or objects  
9 or tangible things containing highly sensitive information,  
10 including technical information and sensitive financial information  
11 that are trade secrets that are not revealed to competitors,  
12 including sales data, pricing, proprietary technical information  
13 concerning product formulations or methods of producing products,  
14 which that party does not reveal to competitors. "Confidential-  
15 Attorneys'-Eyes-Only-Outside Counsel" information is to be treated  
16 in addition with all the protection applicable to Confidential  
17 Information and Confidential-Attorneys'-Eyes-Only provided in this  
18 Order.

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20                 **Disclosure of the Confidential Information**

21         7. Information designated "Confidential" may be used for  
22 purposes of this lawsuit only, and disclosed only to the following  
23 persons:

24                 A. The attorneys and staff of any law firm acting as  
25 outside litigation counsel for a party to this action, and copying  
26

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3 services, data entry and computer support services retained by  
4 outside counsel.

5 B. Independent consultants or experts and their staff not  
6 employed or retained by or affiliated with a party or with a party's  
7 licensee or licensor, who have been retained by the attorneys for  
8 the parties in this action, either as consultants or expert  
9 witnesses for the purposes of this litigation, provided such persons  
10 have complied with the procedures of Paragraph 11 hereof.

11 C. Three (3) attorneys and their clerical staffs employed  
12 by a party in this action; provided that the receiving party  
13 identifies each attorney by name by written notice to the  
14 designating party in advance of any disclosure of Confidential  
15 Information.

16 D. Three (3) persons employed by a party in this action,  
17 who may, but need not be attorneys employed by the party; provided  
18 that the receiving party identifies each employee by name by written  
19 notice to the designating party in advance of any disclosure of  
20 Confidential Information.

21 E. The Court, its staff and personnel, and Official Court  
22 reporters to the extent that Confidential Information is disclosed  
23 at a deposition or court session which they are transcribing.  
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F. Translators not employed by, or affiliated with a party in this action, or a party's licensee or licensor and not employed by, or affiliated with any business entity engaged in the pharmaceutical business, who are retained by the attorneys for the parties for the purposes of this litigation, provided that prior to being given access to any Confidential Information, each such translator reviews and executes a Declaration of Compliance in the form annexed as EXHIBIT I.

G. The list of persons to whom Confidential Information may be disclosed, identified in this Paragraph 7, may be expanded or modified by mutual agreement in writing by counsel for the designating party and the receiving party or parties without necessity or modifying this Order.

H. As used in this paragraph, the term "attorney" includes persons licensed to practice law generally, including persons licensed to practice in any state in the United States, Barristers or Solicitors licensed to practice in Canada, patent attorneys, patent agents or the German or Canadian equivalents thereof.

8. Disclosure of Information to Attorneys.

A. Information designated as "Confidential-Attorneys'-Eyes-Only" shall be disclosed only to the persons described in

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Paragraphs 7(A), (B), (C), (E), (F), and as agreed in accordance with Paragraph 7(G).

B. Information designated as "Confidential-Attorneys'-Eyes-Only-Outside Counsel" shall be disclosed only to (i) attorneys and staff acting as outside litigation counsel who have entered an appearance in this case, (ii) independent experts, (iii) the Court, and (iv) independent translators.

**Use and Control of the Confidential Information**

9. All Confidential Information disclosed pursuant to this Order shall be used by a recipient thereof solely for the purposes of this litigation, and not for any business or competitive purposes, and not for any other civil actions or other proceedings of any type. It shall be the duty of each party and each individual having notice of this Protective Order to comply with this Order from the time of such notice.

10. All depositions, regardless of whether a designation of confidentiality was made on the record or otherwise, shall automatically be treated as having been designated "Confidential-Attorneys'-Eyes-Only-Outside-Counsel" and subject to this Protective Order, unless and until the receiving party makes a request to the party producing the witness or counsel for the witness to release the deposition from "Confidential-Attorneys'-Eyes-Only-Outside-



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Counsel" treatment, and only if, and to the extent, the party producing the witness or counsel for the witness agrees in writing to the modification of treatment of all or part of the transcript, or unless the Court so orders. An entire deposition transcript shall be deemed a single document for purposes of applying the provisions of Paragraph 8 hereof. All Court proceedings during which Confidential Information is likely to be revealed shall be held *in camera*, as to the portion of the hearing, unless the Court orders otherwise.

11. All Confidential Information that is filed with the Court, and any pleadings, motions, memoranda of law, affidavits, expert reports or other papers filed with the Court disclosing any Confidential Information, shall be filed under seal and kept under seal until further order of the Court. Where practicable, only confidential portions of filing with the Court shall be filed under seal.

12. Declaration of Compliance.

A. No person designated in accordance with Paragraphs 7(B), (C), and (D) or Paragraph 8(A) hereof shall have access to Confidential Information without first signing a Declaration of Compliance with the Protective Order in the form annexed as EXHIBIT

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3 I hereto. A file of all such original declarations shall be  
4 maintained by counsel for the party obtaining them.

5 B. Before any persons may be given access to Confidential  
6 Information under Paragraphs 7(B), (C) and Paragraph 8(A), the party  
7 seeking to provide such access must give a copy of the Declaration  
8 referred to in Paragraph 12(A) and written notice (via facsimile) to  
9 the attorneys for the designating party of the intention to make  
10 such disclosure. In the case of disclosure pursuant to Paragraph  
11 7(B), the notice shall state the name and address of the person to  
12 whom disclosure is proposed and include a resume of the background,  
13 qualifications and employment or affiliations of such person. In  
14 the case of a disclosure pursuant to Paragraphs 7(C) and 7(D) and  
15 Paragraph 8(A), the notice shall state the employee's position and  
16 a description of his or her duties.  
17

18 C. For proposed disclosures pursuant to Paragraph 7(B)  
19 only, the designating party, within ten (10) days from receiving  
20 service of such written notice, may object to such disclosure by  
21 service (via facsimile) of a written notice of objection on the  
22 attorneys for the party seeking to make the disclosure, stating the  
23 reasons for objection. No disclosure of Confidential Information  
24 may occur prior to the expiration of ten (10) days from the date of  
25 service of the written notice of intent to disclose unless consent  
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is granted earlier by the designating party, which consent shall not be unreasonably withheld. If the designating party objects to the disclosure and gives written notice thereof, the designating party will have ten (10) business days from the date of service of its objection in which to seek relief from the Court. If the ten (10) business days elapse without the designating party seeking relief from the Court, the proposed disclosure pursuant to Paragraph 7(B) shall be made in accordance with the terms of this Protective Order.

13. Nothing herein shall prevent any party from disclosing its own Confidential Information in any manner that it considers appropriate, nor shall counsel for either party be precluded from showing or using Confidential Information obtained from the opposing party during examination, at deposition or trial, of any officer, employee or retained expert of the party who designated the information confidential.

**Duration of Order, Objections, Modifications**

14. This Protective Order shall remain in force and effect indefinitely until modified, superseded or terminated by Order of this Court, which may be entered pursuant to agreement of the parties hereto. This Order shall continue in effect after termination of these consolidated actions and continue to be binding upon all persons to whom Confidential Information is disclosed hereunder.

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15. Upon final termination of this action (including all appeals) the receiving party shall, within thirty (30) days of such termination, either return to the designating party or destroy all Confidential Information in its possession. In either event, the receiving party shall specifically describe the material returned or destroyed and certify their return or destruction, with the exception that outside counsel may retain one copy of the pleadings or other papers filed with the Court or served in the course of the litigation, deposition transcripts, deposition exhibits and the trial record.

16. If the receiving party learns that Confidential Information produced to it is disclosed to or comes into the possession of any person other than in the manner authorized by this Order, the receiving party responsible for the disclosure must immediately inform the designating party of all pertinent facts relating to such disclosure and shall make every effort to prevent disclosure by each unauthorized person who received such information.

17. Any receiving party may at any time request that the designating party cancel the "Confidential", "Confidential-Attorneys'-Eyes-Only" or "Confidential-Attorneys'-Eyes-Only-Outside Counsel" designation with respect to any document, object or item of

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information. Such request shall be served on counsel for the designating party (via facsimile), and shall particularly identify the designated Confidential Information that the receiving party contends is not confidential and the reasons supporting its contention. If, within ten (10) days from receipt of the request, the designating party does not agree to remove the "Confidential", "Confidential-Attorneys'-Eyes-Only" or "Confidential-Attorneys'-Eyes-Only-Outside Counsel" designation, then the party contending that such documents or information are not confidential may file a motion to remove such information from the restrictions of this Order. On motion to be relieved from the restrictions of this Order, the burden of demonstrating that the information is confidential shall be on the designating party.

**No Waiver of Privileges**

18. Production of documents and things shall not constitute a waiver of confidentiality, privilege or work product as to such documents or any information contained therein so long as the privilege or immunity from discovery is asserted by the designating party in writing no later than thirty (30) days from the date on which such documents shall have been produced to the receiving party. No demonstration or proof of error, inadvertence, or excusable neglect shall be required of the designating party in

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order for such party to avail itself of the provisions of this paragraph.

Other Remedies

19. Nothing herein shall prevent any party or non-party from seeking additional or different relief from the Court not specified in this Order.

20. The section titles in this Order are for the convenience of organization only, and are not part of, nor are they relevant to the construction of this Order.

IT IS SO ORDERED.

San Juan, Puerto Rico, this 17<sup>th</sup> day of September, 1999.



RAYMOND L. ACOSTA  
United States District Judge

EXHIBIT I

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF PUERTO RICO

BAYER AG, et al.,

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DECLARATION OF COMPLIANCE  
WITH PROTECTIVE ORDER GOVERNING CONFIDENTIAL INFORMATION

I, \_\_\_\_\_ do declare and state as follows:

1. I live at \_\_\_\_\_ and  
am employed as (state position) \_\_\_\_\_  
by (state name and address of employer) \_\_\_\_\_.

2. I have read the Protective Order Governing Confidential  
Information entered in these consolidated actions, a copy of which  
has been provided to me.

3. I understand and agree to comply with and be bound by the  
terms of the Protective Order, including the provision that upon  
receipt of any Confidential Information, I will be personally  
subject to it, and to all of its requirements and procedures.

DECLARATION OF COMPLIANCE WITH PROTECTIVE ORDER

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I hereby declare under penalty of perjury under the laws of the United States of America, pursuant to the provisions of 28 U.S.C. § 1746, that the foregoing is true and correct.

Executed this \_\_\_\_ day of \_\_\_\_\_, \_\_\_\_.

At \_\_\_\_\_.

\_\_\_\_\_  
Signature